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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HELLER EHRMAN WHITE & MCAULIFFE LLP			EPPERSON, JON D	
1717 RHODE ISLAND AVE, NW WASHINGTON, DC 20036-3001			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)
	09/856,859	BATTERSBY ET AL.
Office Action Summary	Examiner	Art Unit
	Jon D. Epperson	1639
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet with the c	orrespondence address
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).
Status		
 Responsive to communication(s) filed on 15 E This action is FINAL. Since this application is in condition for allowed closed in accordance with the practice under the condition of the condition is accordance. 	s action is non-final. ince except for formal matters, pro	
Disposition of Claims		
4) ☐ Claim(s) 15-29 is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 15-29 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	wn from consideration.	
Application Papers		
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine 11.	cepted or b) objected to by the l drawing(s) be held in abeyance. See tion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Burea * See the attached detailed Office action for a list	ts have been received. ts have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage
Attachment(s)	4) 🔲 Interview Summary	(PTO.413)
 Notice of References Cited (PTO-992) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/15/05. 	Paper No(s)/Mail Da	

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DETAILED ACTION

Status of the Application

- 1. The Response filed December 15, 2005 is acknowledged.
- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Status of the Claims

3. Claims 15-29 were pending. No claims were added, amended or canceled. Therefore, claims 15-29 are currently pending and examined on the merits.

Withdrawn Objections/Rejections

4. All rejections are maintained and the arguments are addressed below.

Outstanding Objections and/or Rejections

Claims Rejections - 35 U.S.C. 102

5. Claims 15-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (US Patent 4,053,433) (Date of Patent is **October 11, 1977**) as evidenced by Ravkin et al. (US 2003/0008323 A1) (Publication Date is **January 9, 2003**). Please note: MPEP 2131.01(d) permits the citation of references or evidence in an anticipation rejection under 35 U.S.C. § 102 in order to show that a characteristic not disclosed in the reference is inherent.

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For claim 15, Lee (see entire document) discloses methods for making and using a plurality of color-coded microparticles (e.g., see Lee, abstract; see also claims), which anticipates the claimed invention. For example Lee discloses a plurality of carriers (e.g., see Example 1 wherein the fused bundles were cut to provide a "plurality" of carriers; see also Example 2 wherein a plurality of onion microsphere carriers are produced; see also Example 4 wherein a plurality of microsandwich carriers are produced; see also abstract Summary of Invention; see also figures 1-6). Lee does not explicitly state that the plurality of different compounds "can be" synthesized on the carriers. However, the Examiner contends that this "can be" language represents mere "intended use" language or an "optional" step with regard to what is actually synthesized on the plurality of beads and thus is not afforded any patentable weight with regard to limitations that stem from the synthesis. Statements of intended use are not structural limitations that distinguish over the prior art where the prior art is capable of that use. See In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974); In re Yanush, 477 F.2d 958, 959, 177 USPQ 705, 706 (CCPA 1973); In re Casey, 370 F.2d 576, 580, 152 USPQ 235, 238 (CCPA 1967). For example, the use of "detectably distinct" carriers is not required by the current claims. The claims do not state that different compounds "must be" synthesized on the plurality of carriers. Rather, the claims state that a plurality of different compounds "can be" synthesized on said carriers, which renders this step optional. Thus, Applicants' claimed carriers could contain the "same" molecules. Furthermore, Applicants' plurality of carriers need not contain any attached molecules. Thus, codes for distinguishing "detectably distinct" carriers for "identifying" compounds

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"before, during and after" synthesis is not required, as the synthesis in its entirety is entirely optional.

Alternatively, the Examiner contends that this would be an inherent feature of the color-coded microparticles because Lee recognizes that said microparticles are "well suited for the tagging of ... chemicals" (e.g., see column 5, lines 58-60) and Ravkin et al. explicitly state that Lee's microparticles (referred to as "taggants") have been used for just such a purpose (e.g., see Ravkin et al., "The invention further provides for the use of taggants [i.e., the microparticles disclosed by Lee] as coded carriers. In this embodiment, the coded carriers to which the library compounds are attached are taggant particles, such as disclosed in U.S. Pat. Nos. 4,053,433 [i.e., referring to the Lee patent]"). Furthermore, the plurality of carriers includes a population of detectably distinct carriers each having a code, which distinctively identifies a respective carrier before, during and after said synthesis from other carriers, and which is characterized by at least two detectable and/or quantifiable attributes integrally associated with the carrier (e.g., see Summary of Invention, especially, lines 34-49, "The inventory of microparticles may include up to [C][C-1n-1] uniquely coded batches [i.e., the batches are coded "before" any synthesis takes place and would not be changed or altered in any way by a chemical synthesis as exemplified by Ravkin et al. above]; see also column 5, last two paragraphs showing that said microparticles are chemically stable and can even survive a dynamite blast; see also figures 1-6 showing at least two detectable and or quantifiable attributes such as different colors, shapes and sizes). Lee also disclose individual carriers that comprise all the attributes that define a corresponding code before commencing synthesis of a respective

wherein the code is made by the colored layers "independent" of any chemical synthesis). Lee also disclose that the plurality of carries contain at least about 70% detectably distinct carriers (e.g., see Examples wherein all (i.e., 100%) of the carriers are "detectably distinct"; see also Summary of Invention, lines 34-49; see also claim 1, wherein a "unique" code is used to make "identification" and thus "all" of the plurality of carriers [i.e., 100%] are detectably distinct, that is, none of the carriers "lack a code" that would otherwise "dilute" the distinct carrier pool to less than about 70%). Finally, Lee at least two attributes where one of said attributes is not shape, or surface deformation (e.g., see figures 1-6 wherein the at least two attributes represent the at least two colored regions shown or one attribute represents color and the other attribute represents shape; please note that while Applicants' claims preclude one of said attributes from being shape, they do not preclude the other attribute from such a designation).

For *claim 16*, Lee discloses a plurality of carriers wherein at least one of said attributes of a respective carrier is comprised within or internally of the carrier (e.g., see figures 2-4 showing attributes such as elements 28, 30, 34, 38, 40 and 42 "within" the carrier).

For *claims 17-19*, Lee discloses at least one of said attributes of a respective carrier is an electromagnetic radiation-related attribute such as light absorbance (e.g., see Summary of Invention, column 2, lines 28-33, "The improvement in this method, according to the present invention, comprises providing microparticles which comprise

compilations of, and are encoded according to, a particular orderly sequence of <u>visually</u> color distinguishable dyed and/or pigmented layers of organic materials").

For *claim 20*, Lee discloses at least three detectable and/or quantifiable attributes integrally associated therewith (e.g., see Summary of Invention, lines 34-49, wherein an "eight-membered" sequence containing 12 colors per segment results in a system with 233,846,052 possible codes).

For *claim 21*, Lee discloses a fluorescent dye (e.g., see column 6, lines 17-19, "<u>fluorescent</u> color in the code may aid in retrieval of the microparticle"; see also column 3, lines 54-61, "The dyes and pigments used to form the colored layers or segments of the onion microsphere or the microdisc ... include ... inorganic pigments such as sulfates, chromates, sulfides, oxides, carbonates, etc., and stable organic pigments such as phthalocyanine and Hansa Yellow").

For *claim 22*, Lee discloses, for example, "onion" and/or "microsette" particles that fall within the scope of "colloidal" particles because the finely divided pigments are "suspended" in the polymeric matrix (e.g., see Examples 1-2).

For *claim 23*, Lee discloses, various shapes including "spheres" (e.g., see figure 1).

For *claim 24*, Lee discloses different forms including "discs" (e.g., see figures 2-3).

For *claim 25*, Lee discloses different sizes (e.g., see column 3, line 37 disclosing sizes between 50 to 200 micrometers; see also Example 2 wherein different sizes can be

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produced by screening a lot with No. 18, 20 and 25 American Standard screens that contain 1000, 841 and 707 micrometer openings, respectively).

For *claim 26*, Lee discloses, for example, polymeric materials (e.g., see example 2, "Microporous <u>polymeric</u> ion exchange resin beads (Amberlite No. A-26, a quaternary form of a polystyrene resin available from Mallinckrodt Company) about 500-750 micrometers in diameter were used as nuclei for spherical color coded microparticles, i.e., 'onion microspheres.'").

For *claims 27-28*, Lee discloses "glass", which is composed of "silica" (e.g., see column 3, line 33). Lee also disclose a size that is between about 0.01 μ m to about 150 μ m (e.g., see column 3, lines 35-40, "... preparation of microspheres from a variety of substances in a size range preferably 50 to 200 micrometers in diameter"; see also claim 1, "microparticle being 1 to 1000 micrometers at its broadest dimension across the color sequence").

For *claim 29*, Lee discloses, for example, "amines" and "carboxylic acids' (e.g., see Example 2 wherein an amine is disclosed; see also column 3, line 34 wherein an albumin core is disclosed that contains an amino terminus and a carboxylic acid terminus).

Response

6. Applicant's arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified

from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

- [1] Applicants argue, "At no stage are these separate batches of colored microparticles mixed to provide a plurality of detectably distinct colored microparticles. Thus, the Examiner's allegations that Lee discloses a <u>plurality of detectably distinct</u> colored microparticles is erroneous ... As such, a population of <u>identical</u> beads is required to be associated with a given production lot" (e.g., see 12/15/05 Response, page 5, last paragraph).
- [2] Applicants argue, "This reference [Lee] has no relevance whatsoever to organic synthesis on microparticles" (e.g., see 12/15/05 Response, page 6, first full paragraph).
- [3] Applicants argue, "The Examiner believe that the particles of Lee may be used ad "taggants", as disclosed in Ravkin, to which library compounds are attached ... Thus, the Examiner interprets the above attachment as if the compounds are chemically conjugated to taggants. Applicants respectfully disagree and point out that there is neither teaching nor suggestion in either Lee or Ravkin as to how this can be accomplished. Applicants further state that the Examiner's interpretation is even more inconceivable given the disclosure that the particles of Lee are not appropriate for synthesis of different compounds as required by the claims, but rather are for production control of animal feed and grain ..." (e.g., see 12/15/05 response, page 6, fist full paragraph).

This is not found persuasive for the following reasons:

[1] In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "detectably distinct") are not recited in the rejected claim(s). Although the claims are interpreted in light of

the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). For example, the use of "detectably distinct" carriers is not required by the current claims. The claims do not state that different compounds "must be" synthesized on the plurality of carriers. Rather, the claims merely state that a plurality of different compounds "can be" synthesized on said carriers, which renders this step optional. Thus, Applicants' claimed carriers could contain "identical" molecules. Furthermore, Applicants' claims don't require the attachment of "any" molecules. Thus, "detectably distinct" carriers that can "identify" compounds "before, during and after" synthesis are not required, as the synthesis is entirely optional.

Furthermore, Lee <u>inherently</u> discloses this claimed feature as evidenced by Ravkin et al., which explicitly states that Lee's microparticles (referred to as "taggants") have been used for just such a purpose (e.g., see Ravkin et al., "The invention further provides for the use of taggants [i.e., the microparticles disclosed by Lee] as coded carriers. In this embodiment, the coded carriers to which <u>the library compounds are attached are taggant particles</u>, such as disclosed in U.S. Pat. Nos. 4,053,433 [i.e., referring to the Lee patent]"; see also newly amended rejection above).

[2] In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "organic synthesis on microparticles") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Again, the "organic synthesis on microparticles" represents mere "intended use" language or an "optional"

step and thus is not afforded any patentable weight with regard to limitations that stem from the synthesis. Furthermore, Ravkin et al. clearly shows that "organic synthesis" can be performed on these carriers (e.g., see Ravkin et al., "The invention further provides for the use of taggants [i.e., the microparticles disclosed by Lee] as coded carriers. In this embodiment, the coded carriers to which the library compounds are attached are taggant particles, such as disclosed in U.S. Pat. Nos. 4,053,433 [i.e., referring to the Lee patent]").

[3] In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "chemical conjugation") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Again (as outlined at length in sections [1] and [2] above), any "chemical conjugation" represents mere "intended use" language or an "optional" synthesis step and thus is not afforded any patentable weight with regard to limitations that stem from the synthesis. Furthermore, Ravkin et al. clearly shows that organic synthesis "can be" performed on these carriers (e.g., see Ravkin et al., "The invention further provides for the use of taggants [i.e., the microparticles disclosed by Lee] as coded carriers. In this embodiment, the coded carriers to which the library compounds are attached are taggant particles [i.e., the library of compounds is "conjugated" to the taggants], such as disclosed in U.S. Pat. Nos. 4,053,433 [i.e., referring to the Lee patent]").

Accordingly, the 35 U.S.C. §102(b) rejection cited above is hereby maintained.

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Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D. February 24, 2006

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